

## **RESPONSE TO OFFICE ACTION**

### **A. Status of the Claims**

Claims 1, 2, 9, 11, 13, 15, 20-21, 24, 36, 39, 41 and 44 have been amended. Claims 4-8, 16-19, 22-23, 33-34, and 43 are canceled. Claims 1-3, 9-15, 20-21, 24, 30-32, 35-42 and 44-45 are pending and under examination. It is noted that claim 1 has been placed into independent format, and previous independent claim 43 canceled, with dependencies revised accordingly.

### **B. Telephonic Interview**

On March 23<sup>rd</sup>, a telephonic interview was held with the above examiner in charge, the supervisor, Deborah Crouch, and the undersigned, assisted by Dr. Sheila Kadura. During that discussion, the pending rejections were discussed. With respect to the obviousness rejections over Higashijima *et al.*, Applicants requested that they be permitted to submit a declaration of the inventor, Dr. Gong, to substantiate statements made to him by an author of Higashijima, Dr. Okamoto (as corroborated by an email exchange), regarding the inability of fish disclosed in the Higashijima *et al.* article to exhibit a color under normal daylight. Further, Applicants indicated that they would cancel claim 43 (not limited to visibility in daylight), and proceed with claim 1 as the principal claim. While no promises were made, the Examiners indicated that this would likely obviate the rejection over Higashijima *et al.* and Yanong *et al.*

With respect to the remaining rejections, which rely on the Hua *et al.* thesis, Applicants agreed to submit a further declaration of Dr. Gong to demonstrate that the Hua *et al.* thesis was unavailable to the public. Again, while no promises were made, the Examiners agreed that such action would likely obviate the rejections based on the Hua *et al.* thesis.

Applicants thank the Examiners for permitting the foregoing interview.

### C. Rejections on the Basis of Alleged Obviousness

Applicants submit that the obviousness rejections are overcome. As for the rejections based in part on the Hua *et al.* thesis, those rejections are overcome because the Hua thesis was not publicly accessible, and is thus not a “printed publication.” *See* MPEP § 2128. As for the remaining rejections over Higashijima *et al.* and Yanong *et al.*, those rejections are overcome because the references do not disclose fish that display a color that is visible under normal daylight.

#### 1. Rejections Based in Part on the Hua *et al.* Thesis

The Hua thesis has not been shown by the Action to be sufficiently “publicly accessible” to constitute a printed publication. *See* MPEP § 2128 (explaining that a reference is a “printed publication” only if it is accessible to the public). As noted by the Federal Circuit recently, a document is publicly accessible only if it “has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, can locate it and recognize and comprehend therefrom the essentials of the claimed invention without need of further research or experimentation.” *Cordis Corp. v. Boston Scientific Corp.*, 90 USPQ2d 1401, 1411-12, 561 F.3d 1319, 1333 (Fed. Cir. 2009) (quoting *In re Wyer*, 655 F.2d 221, 226 (CCPA 1981) and *I.C.E. Corp. v. Armco Steel Corp.*, 250 F. Supp. 738, 743 (S.D.N.Y.1966)). In general, “[a]ccessibility goes to the issue of whether interested members of the relevant public could obtain the information if they wanted to.” *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1569 (Fed. Cir. 1988).

Many of the Federal Circuit cases in this area have concerned publications available in libraries, and the question has been whether the publication has been sufficiently indexed so as to be publicly accessible. *See, e.g., In re Cronyn*, 890 F.2d 1158, 1161 (Fed. Cir. 1989); *In re Hall*,

781 F.2d 897, 899 (Fed. Cir. 1986); *In re Wyer*, 655 F.2d at 226. In this case, Applicants note that no evidence of record indicates that the Hua thesis was ever available in a library. Instead, as discussed at paragraph 4 of Dr. Gong's Declaration (enclosed at Appendix A), the Hua thesis was, at most, shelved in a departmental reading room.

As Dr. Gong explains at paragraph 3 of his Declaration, the authors of documents C89 and C90 were students in his laboratory enrolled in the Undergraduate Honors Program at the National University of Singapore. He states that the Undergraduate Honors Program is one to which undergraduate students may apply after they have completed 3 years of study, and consists of approximately 70% course work and 30% research. The first semester of the program is said to consist exclusively of course work and in the second semester, in addition to some further course work, the students are required to conduct research and write a lengthy report on their research. Documents C89 and C90 are stated to be examples of such reports. Notably, Dr. Gong confirms that both students worked in his laboratory under his direction and control.

Dr. Gong further explains, at paragraph 4, that he is familiar with departmental practice and that pursuant to such practice, neither document C89 nor C90 would have been transmitted to the National University of Singapore library or to third parties outside of the department. Dr. Gong also states that his department at one time had (but no longer has) a departmental reading room. Documents such as C89 or C90 may have been shelved in that reading room, but Dr. Gong states that the department does not maintain a departmental library. Moreover, Dr. Gong states that the department does not maintain a card catalogue or any other index of Honors Program theses, such as documents C89 and C90.

Finally, Dr. Gong states in paragraph 6 that he personally visited the National University of Singapore library in 2009 and confirmed that neither document C89 nor C90 was listed in the

library card catalogue. Dr. Gong further states that he was unable to otherwise find either document in the library.

Based on the foregoing, the evidence of record demonstrates that the Hua thesis was not accessible to the public because it was not catalogued or indexed in a library. Even if the departmental reading room could be considered a “library,” the Hua thesis was not publicly accessible because, as stated at paragraph 4 of Dr. Gong’s Declaration, the Hua thesis was not catalogued or indexed. The relevant cases state that even when a document is accessible in a library, it is not publicly accessible unless it is catalogued or indexed in a meaningful way. *See, e.g., In re Cronyn*, 890 F.2d at 1161 (“[T]he three student theses were not accessible to the public because they had not been either catalogued or indexed in a meaningful way.”); *In Re Bayer*, 568 F.2d 1357 (CCPA 1978) (holding no public accessibility because “appellant’s thesis could have been located in the university library only by one having been informed of its existence by the faculty committee, and not by means of the customary research aids available in the library”). Here, the Hua thesis was not catalogued or indexed in any way, and thus, it was clearly not “catalogued or indexed in a meaningful way,” as is required for a document shelved in a library to be deemed publicly accessible.

Finally, the Action has not met its burden of demonstrating that the Hua thesis was publicly accessible. It is the PTO’s burden to prove a *prima facie* case that the Hua thesis was publicly accessible, and only after the PTO has made such a *prima facie* case does the burden shift to the Applicants to show that the thesis was not publicly accessible. *In re Lister*, 583 F.3d 1307, 1317 (Fed. Cir. 2009) (holding that “the Board erred in affirming the examiner’s § 102(b) rejection” because the examiner failed to “prove a *prima facie* case of accessibility that would shift the burden to Dr. Lister to show inaccessibility”). The only evidence of record regarding

the accessibility of the Hua thesis was submitted by Applicants in the form of Dr. Gong's Declarations. That evidence establishes that, at most, the Hua thesis was shelved in a departmental reading room (not a library) and was not catalogued or indexed in any way. Such evidence cannot provide *prima facie* proof that the Hua thesis was publicly available.

For these reasons, Applicants submit that the obviousness rejections over the Hua thesis are overcome. Namely, the Hua thesis is not a "printed publication" because it was not available to the public, and the PTO has not made the required showing of accessibility.

2. *Rejection of Claims 1, 36-37, 39-40, 42-44 and 45 Over Higashijima et al. and Yanong et al.*

With respect to the remaining rejections over Higashijima *et al.* and Yanong *et al.*, those rejections are overcome because neither reference discloses fish that display a color that is visible upon exposure to sunlight, as required by the claims. In Dr. Gong's Declaration (enclosed at Appendix A), at paragraph 7, Dr. Gong describes a dialogue with Dr. Okamoto, an author of the Higashijima *et al.* article. During the course of that dialogue, Dr. Gong learned that the fish described in Higashijima *et al.* did not display a visible color under normal daylight.

Specifically, Dr. Gong states in his Declaration that he had a telephone discussion with Dr. Okamoto on November 30, 2007. During that discussion, Dr. Gong and Dr. Okamoto talked about a visit that Dr. Okamoto made to Dr. Gong's aquarium. During that visit to the aquarium, Dr. Okamoto saw the transgenic fluorescent fish described in the 11/749,032 patent application. Dr. Okamoto commented that, in contrast to those fish, the fish described in his publication (Higashijima *et al.*, *Dev. Biol.*, 192:289-299, 1997) did not display a color that was visible under normal daylight. Dr. Okamoto specifically stated that no visible fluorescent color could be seen under normal daylight in the adult green fluorescent protein-expressing fish described in

Higashijima *et al.* During the November 30, 2007 telephone discussion, Dr. Okamoto confirmed this to be the case.

Exhibit 1 to Dr. Gong's Declaration provides email communications between Dr. Gong and Dr. Okamoto that corroborate Dr. Gong's statements. In that email exchange, Dr. Gong wrote the following to Dr. Okamoto:

I understand that you made GFP transgenic zebrafish lines under the alpha-actin promoter and GFP is expressed in zebrafish muscle. This work was published in 1997 by Higashijima *et al.* *Dev. Biol.* 192:289-299. We made GFP and RFP transgenic [sic] zebrafish lines under the mylz2 promoter and they displayed strong visible fluorescent colors in adult fish even under the normal daylight. I recall that when you visited our aquarium [sic] several years ago, ***you mentioned that this visible fluorescent color was not observed in your adult fish of alpha-actin:GFP transgenic lines. You just confirmed the same information over the phone.***

Exhibit 1 (emphasis added). In a responsive email dated December 10, 2007, Dr. Okamoto confirmed that the actin promoter fish described in the Higashijima article did not fluoresce in sunlight. Thus, the evidence of record makes clear that Higashijima *et al.* does not teach fish that fluoresce in sunlight.

Likewise, Yanong *et al.* does not teach fish that fluoresce in sunlight. Yanong *et al.* describes methods for reproductive management of freshwater ornamental fish. The Action relies on the Yanong reference for its disclosure that different varieties of ornamental fish are sold at pet stores or through mail-order catalogues. *See* Action at 12.

Based on the foregoing, it is evident on this record that the combination of Higashijima and Yanong does not meet the limitations of the claims, and there is no other teaching of record that would teach or suggest that the production of transgenic fish that fluoresce in sunlight is desirable or even possible.

#### **D. Non-Statutory Double Patenting**

The Action lastly provisionally rejects claims 1-3, 9-15, 20-21, 24, 30-32 and 35-45 over claims 42-46, 53-55, 58-60, 63-65 and 68-81 of copending Application No. 11/749,032 on the basis of alleged non-statutory obviousness-type double patenting.

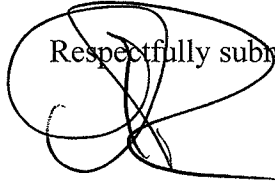
Applicants note that a provisional double-patenting rejection is not a final rejection that blocks the prosecution of all of the conflicting applications. If a provisional double-patenting rejection is the only rejection remaining in an application, the Examiner should withdraw the rejection and permit the application to issue as a patent. MPEP § 804(I)(B). After one application issues as a patent, the provisional double-patenting rejection in the remaining application is converted to an actual double patenting rejection. *Id.* Thus, either the present application or the copending application must issue as a patent before an actual double patenting rejection may be raised against the remaining application.

### CONCLUSION

Applicants believe that the foregoing remarks fully respond to all outstanding matters for this application. Applicants respectfully request that the rejections of all claims be withdrawn so they may pass to issuance.

The Examiner is invited to contact the undersigned attorney at (512) 536-3055 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

A handwritten signature in black ink, appearing to be "David L. Parker", written over the words "Respectfully submitted,".

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